ONCORE

BIOCARE MEDICAL

RISHzyme™ for ONCORE

Enzyme Pretreatment Reagent for *in situ* Hybridization Procedures on the ONCORE Automated Slide Stainer

Control Number: 901-6039K-012715

ISO 9001&13485 CERTIFIED

Catalog Number: ORI6039K T120

Description: 120 tests

Intended Use:
For In Vitro Diagnostic Use
RISHzyme™ for ONCORE is a buffered digestive enzyme solution intended for use in pretreatment of formalin-fixed, paraffin-embedded (FFPE) tissues in an *in situ* hybridization (ISH) procedure performed on Biocare Medical's ONCORE Automated Slide Stainer. The clinical interpretation of any staining or its absence should be complemented by morphological studies and proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Summary & Explanation:
RISHzyme™ for ONCORE is a digestive enzyme used in the pretreatment of formalin-fixed paraffin-embedded tissues (FFPE) to enhance probe accessibility to nucleic acid targets. In FFPE tissues, certain *in situ* hybridization protocols require enzymatic pretreatment for proper ISH staining. RISHzyme™ is an aggressive enzyme and can be used at room temperature or at 37°C. Certain tissues require this type of aggressive enzyme digestion prior to heat retrieval for optimal results. When used in combination with RISH™ Retrieval for ONCORE, a synergistic effect on probe accessibility to nucleic acid targets may be achieved. This product is provided as a two-component system and may be prepared at various concentrations, as desired by the user.

Known Applications:
in situ hybridization (FFPE tissues)

Supplied As:
RISHzyme™ for ONCORE is supplied as two solutions, concentrated enzyme and buffer with preservative, intended to be mixed prior to use:
RISHzyme™ (ORI6022 G3) 3 mL
RISHzyme™ Buffer (ORI6023 T30) 30 tests, 4 vials x 6.7 mL

Reconstitution, Dilution and Mixing:
RISHzyme™ for ONCORE is provided as an enzyme concentrate with buffer for dilution. Add 7 drops of RISHzyme™ to 1 buffer vial for a 1:25 dilution. Add 3-4 drops of RISHzyme™ to 1 buffer vial for an approximate 1:50 dilution.

RISHzyme™ Buffer incorporates a color-coded pH indicator. The end-user can visually inspect the solution and see that the mixture or buffer is at the proper pH. If the mixed solution is purple, the pH is too high for optimal digestion. If the buffer or RISHzyme™ solution turns orange or yellow, the pH is too low for optimal digestion.

Materials and Reagents Required But Not Provided:
Reagents and materials, such as RISH™ *in situ* probes, detection kits, chromogens and ancillary reagents are not provided. Refer to the ONCORE Automated Slide Staining System User Manual for a complete list of materials and reagents required.

Storage and Stability:
Store at 2ºC to 8ºC. Do not use after expiration date printed on vial. The working solution is stable for 14 days after addition of RISHzyme™ to RISHzyme™ Buffer, when stored at 2°C to 8°C.

Instructions for Use:
Mix RISHzyme™ in RISHzyme™ Buffer as desired (see Reconstitution, Dilution and Mixing). Cap the vial and invert several times to thoroughly mix contents. Uncap the vial and place in the ONCORE reagent tray.

The ONCORE will apply reagent as required in the selected protocol. Refer to the ONCORE Automated Slide Staining System User Manual for detailed instructions on instrument operation and additional protocol options.

Limitations:
This reagent has been optimized for use with ONCORE RISH™ probes, detections and ancillary reagents. The protocols for a specific application can vary. These include, but are not limited to fixation, enzymatic digestion, heat-retrieval method, incubation times, and tissue section thickness. Third party ISH probes may be used on the ONCORE; however, appropriate probe concentration and protocol parameters may depend upon multiple factors and must be empirically determined by the user. Ultimately, it is the responsibility of the investigator to determine optimal conditions. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

Quality Control:
Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assays; Approved Guideline-Second Edition (I/LA28-A2). CLSI Wayne, PA, USA (www.clsi.org). 2011

Precautions:
1. This product is intended for *in vitro* diagnostic (IVD) use.
2. This product is classified as non-hazardous based on the concentrations and hazards of the components, in compliance with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), the US OSHA Hazard Communication Standard (HCS), and European Union Classification, Labeling, and Packaging (CLP) regulations.
3. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Avoid contacting the skin and mucous membranes with reagents and specimens, and follow standard laboratory precautions to prevent exposure to eyes and skin. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water. (3)
4. Microbial contamination of reagents may result in an increase in nonspecific staining.
5. The SDS is available upon request and is located at http://biocare.net/.

Troubleshooting:
Follow the reagent specific protocol recommendations according to the data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

References:
1. Wilkinson DG. In Situ Hybridization: A Practical Approach (Practical Approach Series). 2nd Ed. Oxford: Oxford University Press, 1999.
2. Nuovo GJ. In Situ Molecular Pathology and Co-Expression Analyses. 1st Ed. San Diego: Academic Press, 2013.
3. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.

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